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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,427	05/10/2005	Hans-Georg Capraro	ON/4-32759A	5061
75/074 75/90 05/12/2009 NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC. 220 MASSACHUSETTS AVENUE CAMBRIDGE, MA 02139				
EXAMINER				
MOORE, SUSANNA				
ART UNIT		PAPER NUMBER		
1624				
MAIL DATE		DELIVERY MODE		
05/12/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,427

Applicant(s)

CAPRARO ET AL.

Examiner

SUSANNA MOORE

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/18/2009 has been entered.

Response to Arguments

Applicant's argument, see Remarks, filed 2/18/2009, with respect to Office Action mailed 8/18/2008 have been fully considered. Some of the rejections have been withdrawn, while others have been maintained. Thus, this is a **Final** Office Action. In summary, claims 1, 7 and 9 are currently pending and under consideration.

Claim Rejections - 35 USC § 112

The rejection of claims 1-7 and 9 under 35 U.S.C. 112, second paragraph, as being indefinite for the terms "unsubstituted or substituted" is **withdrawn** based on the amendments.

The rejection of claims 1-6 and 9 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **withdrawn** based on the amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirst et. al. (U.S. 6,713,474).

The instant invention claims compounds of formula (I), wherein R¹= hydrogen, R²= 4-methylpiperazinyl, X= oxygen and R⁴= benzyl and X-R⁴ is at the 3 position of the phenyl ring.

The reference teaches a compound of formula (I), wherein R^1 = hydrogen, R^2 = 4-methylpiperazinyl, X= oxygen and R^4 = benzyl. See column 130, lines 53-55. Another species found in the reference is a compound of formula (I), wherein R^1 = hydrogen, R^2 = 4-methylpiperazinyl, X= oxygen and R^4 = benzyl and and X- R^4 is at the 4 position of the phenyl ring.. See column 130, lines 53-55.

The difference between the claimed compound and the reference is the position of the X- R^4 on the phenyl ring, the 4 position versus Applicant's 3 position. The MPEP 2144.09 states "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus)... are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

Moreover, the generic structure of Hirst encompasses the instantly claimed compounds (see Formula I, column 9) as claimed herein. Columns-9-12, define the substituents as follows: R^1 is hydrogen, substituted or unsubstituted aliphatic group, halogen; R^2 is substituted or unsubstituted cycloalkyl group, etc.; X= O, NH, S; and R^4 = is substituted or unsubstituted aralkyl group, substituted or unsubstituted heteroaralkyl group, etc. The compounds of the instant invention are generically embraced by Hirst in view of the interchangeability of the substitutions of the pyrrolo[2,3-d]pyrimidine. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example NHCH₂phenyl for X- R^4 as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

The same arguments applied above can be directed towards the following references: U.S. 2003175935, 2003082622, 2003153752; WO 2001072751 and 2000017202. These references have the same specie listed above in the art rejection. The references also teach genus equivalency teachings of the substituents.

Applicant states the same traversal as previously, "In applying the test for obviousness to chemically similar structures, the Court of Appeals Federal Circuit recently laid out a standard in *Takeda Chemical Industries Ltd v. Alphabarm Pty. Ltd.* 83 USPQ2d 1169 (Fed. Cir. 2007). The Court stated, "in many cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish a prima facie case of obviousness in order to find a prima facie case of obviousness (for structurally related compounds), a showing that the 'prior art would have suggested making the molecular modifications necessary to achieve the claimed invention' was also required."

First of all, whether the compound is buried in a reference or is on the cover of a scientific journal does not matter. A reference, which cites a compound of interest and which is available to public, is considered relevant. Secondly, as noted in the above rejection, a positional isomer is generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. This is all the motivation necessary to render a compound obvious.

Applicant goes on to state, "The Examiner rightly states, "whether the compound is buried in a reference or is on the cover of a scientific journal does not matter. A reference, which cites a compound of interest and which is available to the public, is considered relevant."

A reference however, must be viewed as a whole in terms of what it teaches however. In the present case, Hirst broadly discloses close to 600 compounds which are broadly defined as being protein kinase inhibitors. There are at least 400 enzymes identified as protein kinases. Each protein kinase has its own unique structural properties and therefore unique small molecules which would inhibit it. There is no data presented in Hirst suggesting that the compounds contained therein would potently inhibit IGF-IR, whether it be on its face or in column 130. Absent any data for the compounds, there is not evidence that any compounds included therein would potently inhibit IGH-IR. It would therefore be a further stretch to suggest that a positional isomer of such a compound would inhibit IGF-IR, since the compounds themselves have not been demonstrated as inhibiting IGH-IR.”

Applicant is claiming a compound, not a method of intended use. Thus, the rejection is **maintained**.

All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624
/Brenda L. Coleman/
Primary Examiner, Art Unit 1624